

Attorney Docket No.: 5784.210-US  
USSN: 09/671,461  
Filed: 09/27/2000  
Inventor: Arne Staby

### **REMARKS**

Claims 2, 4, 6 and 11-21 are pending following entry of the present amendments.

Applicant recognizes that entry of amendments to the claims after a final rejection is not a matter of right but requests entry of the above amendments for the following reasons. First, as added claims 16-21 find support inter alia in claims 6 and 11-15 and depend from a claim (claim 4) that the Examiner has found to be free of the prior art, Applicant submits that entry of these added claims does not add new matter and will not require any further search by the Examiner. Second, with respect to the amendments to claims, 6, 11, 12 and 15, these amendments are believed to address rejections set forth by the Examiner in the present Office Action and therefore reduce issues that might arise on appeal.

### **Rejections Of The Claims Under 35 U.S.C. 112, Second Paragraph**

The Examiner rejected claims 6, 11, 12 and 15 as indefinite because:

- 1) Claims 6 and 15 depend from cancelled claim 1;
- 2) of the recitation "derivatives thereof" in claims 11 and 12; and
- 3) of the use of the term "B28IsoAsp insulin" in claim 15 as it is not clear what "IsoAsp" is.

Applicant respectfully traverses these rejections.

With respect to the first and second grounds of rejection, Applicant submits that the amendments to claims 6, 11, 12 and 15 render these rejections moot and that the deletion of the phrases "as well as homologs, analogs and derivatives thereof" in claim 11 and "and analogs, as well as derivatives thereof" in claim 12 is made because these phrases are redundant with the remainder of the claims.

With respect to the third ground of rejection, Applicant submits that the term "IsoAsp" was clearly understood in the art to mean isoaspartate (see, for example, description of Figure 5 of US patent 5,273,826 entitled "Determination of isoaspartate in proteins") and that the phrase "B28IsoAsp insulin" was previously found to be clear and definite in its meaning by

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the Patent Office as referring to human insulin in which the amino acid at position 28 of the B chain is IsoAsp as evidenced by the inclusion of this phrase in claim 7 of the US patent 6,451,987 that issued from parent application 09/522,694.

Accordingly, in view of the above amendments and remarks, Applicant respectfully requests withdrawal of this rejection.

**Rejection Of The Claims Under 35 U.S.C. 102 (e)**

The Examiner rejected claims 2, 6, 1, 13 and 14 under section 102 (e) as anticipated by Korc et al (US 2003/0103980 A1, priority date October 16, 1998).

Applicant respectfully traverses this rejection.

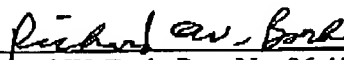
In independent claims 2 and 4, step a) refers to washing the column at a certain pH to elute impurities and step b) then refers to **eluting the peptide of interest from the column at the same or lower pH than in step a.** By comparison, the buffers D and E applied sequentially in paragraph 0068 of Korc to wash the DEAE column to remove impurities (as alleged by the Examiner) are at pH 8.0 and 3.5 respectively and Korc then discloses that after the wash with buffer E, the pH is then adjusted back to pH 8.0 and that the peptide of interest (glypican or syndecan) is then eluted with buffer F (50 mM tris-HCl, pH 8.0, 0.75M NaCl, 0.1% triton X-100). Accordingly, since buffer E in Korc is at pH 3.5 and the buffer used to elute the glypican is at pH 8.0, **the method used by Korc does not meet the limitation of step b of claims 2 and 4 that the pH used in step b) be the same or lower pH as the pH in step a** and hence cannot anticipate the claims as alleged by the Examiner. Accordingly, withdrawal of the §102 (e) rejection is therefore respectfully requested.

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In view of the above amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and early and favorable consideration to that end is respectfully requested

Respectfully submitted,

Date: December 15, 2004

  
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